et al. Attorney's Docket No.: 06275-004003 / D 1271-7 US Continuation

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## AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listings of claims in the application:

## Listing of Claims:

## 1.-20. (Canceled)

- 21. (new) A propellant-free composition comprising (A) a polypeptide, and (B) one or more surfactant compounds that (i) have a consistency that permits them to be processed into primary particles having a diameter less than 10 microns, and (ii) enhance the systemic absorption of said polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device, wherein at least 50% of the total mass of (A) and (B) consists of primary particles having a diameter less than or equal to about 10 microns, said primary particles optionally being formed into agglomerates; and
- a pharmaceutically acceptable carrier comprising particles having a diameter of at least 20 microns, such that an ordered mixture is formed between (A) and (B) and the carrier.
- 22. (new) The composition of claim 1, wherein said polypeptide is a polypeptide hormone.
- 23. (new) The composition of claim 2, wherein said hormone is vasopressin, desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), somatostatin, gonadotropin agonist, human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.
- 24. (new) The composition of claim 1, wherein said polypeptide is a growth factor, interleukin, polypeptide vaccine, enzyme, endorphin, glycoprotein, lipoprotein, or polypeptide involved in the blood coagulation cascade, that exerts its pharmacological effect systemically.

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25. (new) The composition of claim 1, wherein said polypeptide has a molecular weight of less than 30 kD.

- 26. (new) The composition of claim 1, wherein said polypeptide has a molecular weight of less than 25 kD.
- 27. (new) The composition of claim 1, wherein said polypeptide has a molecular weight of less than 20 kD.
- 28. (new) The composition of claim 1, wherein said polypeptide has a molecular weight of less than 15 kD.
- 29. (new) The composition of claim 1, wherein said polypeptide has a molecular weight of less than 10 kD.
- 30. (new) The composition of claim 1, wherein at least one of said one or more surfactant compounds is a bile salt, an alkyl glycoside, a cyclodextrin or derivative thereof, a single-chain phospholipid, or a double-chain phospholipid in which each chain of the double-chain phospholipid is eight or fewer carbon atoms in length.
- 31. (new) The composition of claim 1, wherein at least one of said one or more surfactant compounds is a salt of a fatty acid.
- 32. (new) The composition of claim 11, wherein said fatty acid has 10-14 carbon atoms.
- 33. (new) The composition of claim 12, wherein said fatty acid is capric acid.
- 34. (new) The composition of claim 1, wherein at least one of said one or more surfactant compounds is sodium caprate.
- 35. (new) The composition of claim 1, further comprising one or more non-hygroscopic additives.

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36. (new) The composition of claim 15, wherein the one or more additives are selected from the group consisting of lactose, glucose, raffinose, melezitose, lactitol, maltitol, trehalose, sucrose, and mannitol.

- 37. (new) The composition of claim 1, wherein the primary particles are not agglomerated.
- 38. (new) A method for systemic administration of a biologically active polypeptide to a patient, comprising

providing the composition of claim 1; and

causing said patient to inhale said composition from a dry powder inhaler device for a time and under conditions effective for the polypeptide to be absorbed through epithelial cells of the lower respiratory tract.

- 39. (new) A dry powder inhaler device containing the composition of claim 1.
- 40. (new) The dry powder inhaler device of claim 34, said inhaler device being a multi dose, breath actuated, dry powder inhaler for multiple use.